IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' REPLY IN SUPPORT OF MOTION
TO EXCLUDE THE TESTIMONY OF DR. JIMMY MAYS, PH.D.

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this Reply in Support of their Motion to Exclude the Testimony and Opinions of Dr. Jimmy Mays, Ph.D. [ECF No. 2144 ("Motion")] and Memoranda in Support [ECF No. 2074 ("Defs.' Mem.")]. Ethicon requests that the Court grant its Motion and reject the arguments raised in Plaintiffs' Response to the Motion [ECF No. 2144 ("Response")].

I. Plaintiffs ignore Dr. Mays's admission that Prolene is different than pure polypropylene.

The central argument in Plaintiffs' Response is that Dr. Mays should be permitted to testify about the alleged degradation of Prolene based on their unsupported assertion that Prolene is no different from other forms of polypropylene. *See* Resp. at 4. In making this argument, Plaintiffs ignore the sworn testimony of their own experts in this case, including Dr. Mays, who admit that Prolene's added antioxidant packages makes it unique and different from pure polypropylene as well as other blends including polypropylene. *See* Defs.' Mem. at 3–4. Tellingly, Plaintiffs' Response side-steps this point altogether, failing to even acknowledge—

much less address—this sworn testimony of its experts. Instead, Plaintiffs dismiss the fact that Prolene is different and distinct from other polypropylene products as "nonsense" because "Prolene is 99.8 percent polypropylene." Resp. at 4. Plaintiffs ignore the fact that that the remaining 0.2% is the antioxidant package that differentiates Prolene from other forms of polypropylene. Response Ex. B, 3/2/2016 Mays Dep. Tr. 30:15-24 (explaining that "Prolene is a particular formulation of polypropylene" with "different additives," "different molecular weights," and "different molecular weight distributions"). Plaintiffs' position has no basis in science, evidenced by their failure to cite any scientific support for the claim. *See* Resp. at 4.

II. Dr. Mays's degradation opinions about Prolene are unsupported by testing.

Ethicon explained in its Motion that Dr. Mays has not tested Prolene, even though he (i) believes testing is necessary to determine whether a material has degraded, and (ii) has tried to base his degradation opinions on testing conducted on different polymers in litigation against other pelvic mesh manufacturers. Defs.' Mem. at 4. Ethicon then argued that "[h]aving failed to conduct any tests on Prolene, Dr. Mays seeks to base his degradation opinions on his review of scientific literature and certain internal Ethicon documents," but none of these studies support his opinion that Prolene degrades *in vivo*. *Id.* at 5–11. Because Dr. Mays failed to support his degradation opinions about Prolene in this litigation with scientific testing or literature, Ethicon argued that the Court should exclude his opinions. *See generally id.*

Although Ethicon has never argued that testing is an absolute prerequisite to admissibility, at least one Virginia federal court has held that an expert's failure to test his opinions can warrant exclusion. *See Hodges v. Federal-Mogul Corp.*, No. 7:12-cv-00362, 2014 WL 901214 at *9 (W.D. Va. Mar. 7, 2014) ("[T]he absence of physical testing or modeling in an expert's methodology can impact the reliability of that expert's opinion. The Fourth Circuit has

repeatedly upheld district court decisions excluding expert opinions as unreliable due to a lack of testing.").

Despite Plaintiffs' transparent attempt to muddy the waters, Ethicon argued clearly in its Motion that Dr. Mays's opinions regarding the alleged degradation of Prolene are unreliable because he has not tested the unique material. If Ethicon's mesh was made of pure polypropylene, then arguably Dr. Mays would not be required to test an actual explant. It is not. The substance at issue is Prolene which, by Dr. Mays's own admission, is distinct and different from pure polypropylene, and Dr. Mays has simply failed to test it — even though he believes testing is necessary.

III. Dr. Mays's degradation opinions about Prolene are unsupported by the scientific literature.

As explained in Ethicon's Motion, Dr. Mays's opinions are unreliable because they are unsupported by relevant scientific literature. Specifically, Ethicon noted that much of the scientific literature on which Dr. Mays relies simply does not address the product at issue in this litigation—Prolene—and is, therefore, irrelevant. Motion at 6. Ethicon also explained that even the studies that do include Prolene—*i.e.*, the Jongebloed, Costello, and Mary studies—do not support his opinions that the Prolene in Ethicon's mesh products degrades *in vivo*. *See* Defs.' Mem. at 6–9.

Plaintiffs first resort to their erroneous and unsupported assumption that Prolene is indistinguishable from other forms of polypropylene. But Plaintiffs cite no legal or scientific authority for the proposition that an expert can rely on a study about a product that is similar to, but materially different from, the product on which he seeks to opine.

Plaintiffs then suggest that Dr. Mays relied on "hundreds" of peer-reviewed scientific articles to support his opinions in this litigation, but concede that "only a small piece" of his

literature pool addresses Prolene specifically. Resp. at 8. Tellingly, the only papers Plaintiffs' Response specifically identifies are the Jongebloed, Costello, and Mary papers addressed in Ethicon's Motion. *See* Resp. at 8. And while Ethicon explained in detail why these papers are inapposite (Defs.' Mem. at 7–9), Plaintiffs' Response does not rebut Ethicon's arguments.

A. The Jongebloed and Costello Papers are inapposite.

As discussed in Ethicon's Motion, the Jongebloed paper is irrelevant because it exposed the Prolene sutures to ultraviolet radiation, which is known to oxidize Prolene but is not present in the female pelvic floor. *See* Defs.' Mem. at 7. Ethicon also explained that Dr. Mays's reliance on the Costello papers is misplaced because one of the papers did not include Prolene at all, and the other reported evidence of degradation of a mesh manufactured by a different company, but expressly found that the Ethicon "'specimen did not possess any visible surface degradation.'" *Id.* at 7–8.

These papers are clearly irrelevant to the Prolene used in Ethicon's mesh products, yet Plaintiffs' Response does not even attempt to rebut these arguments. *See* Resp. at 8. Plaintiffs' failure to address these arguments speaks volumes.

B. Plaintiffs' efforts to rehabilitate the Mary study do not withstand scrutiny.

As discussed in Ethicon's Motion, the Mary study does not support Dr. Mays's opinions because it used an unreliable methodology. *See* Defs.' Mem. at 8–9. Specifically, Ethicon explained that the authors' conclusions based on FTIR were flawed because they failed to recognize that one of the antioxidants used in Prolene has the same carbonyl peak that the authors assumed was evidence of oxidation. *Id.* at 9. Ethicon also showed that the sample preparation process used in the Mary study confounded SEM analysis because the specimens

were coated with proteins and then exposed to formalin or gluteraldehyde, both of which crosslink with proteins to form a brittle shell that appears as a cracked surface under SEM. *Id.*

Plaintiffs dispute Ethicon's argument regarding the Mary study's FTIR analysis on the basis of Dr. Mays's testimony that the authors "cleaned the sample and that would remove surface antioxidants," and that the two-year implant time would "deplete antioxidants present at the surface." Resp. at 9 (quoting Mays 3/2/2016 Dep. Tr. 124:8-13). This is classic *ipse dixit*.

Nothing in the Mary article suggests that the cleaning process would remove surface antioxidants, and neither Dr. Mays's Report nor his deposition testimony contain any suggestion that he ever analyzed whether the Mary cleaning process will remove antioxidants. *See* Defs.' Mem. Ex. L, C. Mary, *et al.*, *Comparison of the* In Vivo *Behavior of Polyvinylidene Flouride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc'y Artificial Internal Organs J. 199 (1998). Similarly, Dr. Mays's suggestion that the antioxidants depleted *in vivo* is pure speculation because he admitted at deposition that he could not quantify the rate of any alleged antioxidant depletion. Response Ex. B, Mays 3/2/2016 Dep. Tr. 89:16-90:9. For this reason, despite Plaintiffs' unfounded assertion to the contrary, it cannot be said with any degree of scientific certainty that the Mary study's FTIR testing identified oxidation, rather than Prolene's antioxidant package. *See also* Defs.' Mem. at 9.

Plaintiffs also dispute Ethicon's argument regarding the Mary study's SEM analysis. Curiously, while Plaintiffs assert that Ethicon's argument is based on a "flawed" theory, Plaintiffs acknowledge the legitimacy of Ethicon's position by claiming that the Mary study did,

in fact, remove the cross-linked formalin or gluteraldehyde layer. Resp. at 10.[1] Plaintiffs fail to recognize that the cleaning protocol used in the Mary study only applied to the specimens that underwent morphologic and chemical analysis, but not the SEM analysis that is the subject of Ethicon's argument. *See* Motion Ex. L, Mary Study at 200.

Although an expert can base his opinions on reliable scientific literature, the literature must actually stand for the proposition for which it is cited in order for the expert's opinion to be considered reliable. The Mary study simply does not support the Dr. Mays's opinion that Prolene is subject to oxidative degradation, and none of Plaintiffs' arguments to the contrary can withstand scrutiny.

IV. Neither Ethicon's internal studies nor the MSDS support Dr. Mays's opinions.

Plaintiffs wrongly claim that Ethicon's Motion "ignores the conclusions of its own scientists regarding the oxidative degradation and embrittlement of its Prolene blend *in vivo*." Resp. at 11. Far from ignoring these materials, Ethicon's Motion explains in detail why these internal studies do not support Dr. Mays's opinions. Defs.' Mem. at 10–11.[2]

The only substantive argument Plaintiffs advance is that Ethicon denies that its internal studies found evidence of degradation because they did not find a loss of molecular weight. Resp. at 12–13. Without any basis in the literature or science, Plaintiffs claim that "loss of

[1] Plaintiffs rely on the Zhang and Fraenkel-Conrat studies, both of which Dr. Thames relies in opining that formalin or gluteraldehyde causes a protein-fixed hard and brittle shell on the surface of the explant. *See* Defs.' Mem. Ex. M, Thames Report at 17 & n.80. Plaintiffs fail to explain how Ethicon's position is simultaneously "flawed" and a "well-known and well understood chemical reaction."

[2] In claiming that Ethicon seeks to introduce evidence of FDA's approval and regulation of Prolene sutures "if Dr. Mays is allowed to testify that Prolene degrades," Plaintiffs misstate Ethicon's argument. Resp. at 12. As clearly explained in Ethicon's Motion, Ethicon believes that if Dr. Mays is allowed to testify about Ethicon's suture studies, the Court should permit Ethicon to introduce evidence that FDA approved Prolene sutures as safe and effective. *See* Defs.' Mem. at 11–12. The Court should reject Plaintiffs' unfounded arguments on this issue.

molecular weight is not a fundamental component of oxidative degradation." That statement is completely inconsistent with Dr. Mays's sworn testimony in this case:

> Q: Doctor, there must be a loss of molecular weight for degradation to occur, correct?
>
> A: Must be a loss of? Well, with polymers, if you're talking about oxidation degradation of polypropylene, you will see a reduction in molecular weight.

Response Ex. B, Mays 3/2/2016 Dep. Tr. 79:3-8.

Plaintiffs' argument is also inconsistent with the scientific authority on oxidative degradation. *See, e.g.,* Reply Ex. S, G. Wypych, Handbook of Material Weathering, 424–27 (2008) (advising that an increase in carbonyl concentration and decrease in molecular weight will accompany any oxidative degradation of polypropylene); Reply Ex. T, H. Zweifel, *et al.*, Plastics Additives Handbook, *Antioxidants,* at 5–6 & Scheme 1.3 (2009) (reporting that degradation is accompanied by mechanical deterioration, molecular weight changes, molecular weight distribution changes, and an increase in carbonyl groups); Reply Ex. U, M. Gahleitner & J. Fiebig, Polypropylene: An A-Z Reference, *Long Term Properties and Lifetime Prediction for Polypropylene*," 394 (1999) (explaining that degradation "reduc[es] the average chain length of the polymer and especially affecting the high molar weight fraction" which cause "a significant reduction of mechanical properties," including "embrittlement" and "a massive decrease in toughness"). Indeed, Ethicon's internal studies found "no molecular weight degradation." Reply Ex. V, ETH.MESH.09888221.

Finally, Plaintiffs argue the MSDS cautions that Prolene can be reactive with "strong oxidizing agents." However, Plaintiffs fail to identify any such agent that would be present *in vivo* and provide no scientific support Plaintiffs' arguments regarding Ethicon's internal studies and the Prolene MSDS lack merit, and should be disregarded by this Court.

V. Dr. Mays is unqualified to opine about clinical complications, and his opinions are unreliable.

Ethicon argued in its Motion that the Court should preclude Dr. Mays from offering opinions regarding the clinical complications allegedly caused by the degradation because he lacks the requisite qualifications and his opinions are not reliable. Defs.' Mem. at 12–14. Plaintiffs do not actually respond to Ethicon's arguments. Resp. at 14.

Instead, Plaintiffs simply claim that Dr. Mays should be allowed to testify about clinical complications because he claimed that he is qualified to do so at deposition, and he has allegedly informed students and some of his colleagues that polypropylene can degrade which can cause some unspecified bodily harm. Resp. at 14. None of the testimony Plaintiffs cite demonstrates that Dr. Mays has the specialized knowledge, education, training, skill, or experience to opine about questions of medical causation, and the Court should reject Plaintiffs' argument for this reason. *See* Fed. R. Evid. 702.

VI. Conclusion

For all of these reasons, as well as those set forth in Ethicon's Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Dr. Jimmy Mays.

Respectfully submitted,

/s/ David B. Thomas
David B. Thomas (W.Va. Bar #3731)
Thomas Combs & Spann PLLC
300 Summers Street
Suite 1380 (25301)
P.O. Box 3824
Charleston, WV 25338
(304) 414-1800
dthomas@tcspllc.com

/s/ Christy D. Jones

Christy D. Jones
Butler Snow LLP
1020 Highland Colony Parkway
Suite 1400 (39157)
P.O. Box 6010
Ridgeland, MS 39158-6010
(601) 985-4523

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON

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CERTIFICATE OF SERVICE

I hereby certify that on May 14, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ David B. Thomas

David B. Thomas (W. Va. Bar No. 3731)
Thomas Combs & Spann, PLLC
300 Summers Street, Suite 1380
P.O. Box 3824
Charleston, WV 25338-3824
(304) 414-1800

COUNSEL FOR DEFENDANTS ETHICON, INC. AND JOHNSON & JOHNSON